

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS  
(BOSTON)**

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In re: New England Compounding  
Pharmacy, Inc. Products Liability  
Litigation.

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**MDL No. 1:13-md-2419-FDS**

This Document Relates To:

WARREN L. SMITH and  
KAREN F. SMITH,

Plaintiffs,

v.

**CASE No: 1:13- cv-10559**

AMERIDOSE LLC, MEDICAL SALES  
MANAGEMENT INC., GDC  
PROPERTIES MANAGEMENT, LLC,  
BARRY J. CADDEN, LISA  
CONIGLIARO CADDEN, GLENN A.  
CHIN, GREGORY CONIGLIARO, and  
ARL BIO PHARMA, INC. d/b/a  
ANALYTICAL RESEARCH  
LABORATORIES,

Defendants.

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**ANSWER, AFFIRMATIVE DEFENSES, AND JURY DEMAND OF ARL BIO  
PHARMA, INC. d/b/a ANALYTICAL RESEARCH LABORATORIES IN  
RESPONSE TO WARREN AND KAREN SMITH'S COMPLAINT**

**ANSWER**

The defendant, ARL BioPharma, Inc. d/b/a Analytical Research Laboratories  
("ARL"), hereby Answers the Plaintiffs' Complaint in this lawsuit ("Lawsuit") as  
follows:

### **INTRODUCTION**

1. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 1 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.
2. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 2 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.
3. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 3 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

### **PARTIES**

4. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 4 of the Complaint.
5. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 5 of the Complaint.
6. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 6 of the Complaint.
7. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 7 of the Complaint.

8. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 8 of the Complaint.
9. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 9 of the Complaint.
10. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 10 of the Complaint.
11. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 11 of the Complaint.
12. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 12 of the Complaint.
13. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 13 of the Complaint.
14. ARL admits the allegations set forth in Paragraph 14 of the Complaint.

#### **JURISDICTION AND VENUE**

15. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 15 of the Complaint.
16. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 16 of the Complaint.
17. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 17 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

18. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 18 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

### **STATEMENT OF THE FACTS**

#### **F. RELEVANT BACKGROUND (SIC)**

19. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 19 of the Complaint.
20. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 20 of the Complaint.
21. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 21 of the Complaint.
22. ARL states that Massachusetts 247 CMR 2.00 and 6.07 speak for themselves and, to the extent that the allegations of Paragraph 22 of the Complaint are inconsistent with 247 CMR 2.00 and 6.07, ARL denies the allegations.
23. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 23 of the Complaint as they pertain to NECC. Insomuch as Paragraph 23 references 247 CMR 6.02(1), ARL states that Massachusetts 247 CMR 6.02(1) speaks for itself and, to the extent that the allegations of Paragraph 23 of the Complaint are inconsistent with 247 CMR 6.02(1), ARL denies the allegations.

24. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 24 of the Complaint.
25. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 25 of the Complaint.
26. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 26 of the Complaint. .
27. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 27 of the Complaint.
28. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 28 of the Complaint.
29. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 29 of the Complaint.
30. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 30 of the Complaint.
31. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 31 of the Complaint.
32. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 32 of the Complaint.
33. ARL states that its website speaks for itself and, to the extent that the allegations of Paragraph 33 of the Complaint are inconsistent with the website or taken out of context, ARL denies the allegations.

34. ARL states that its website speaks for itself and, to the extent that the allegations of Paragraph 34 of the Complaint are inconsistent with the website or taken out of context, ARL denies the allegations.
35. ARL states that its website speaks for itself and, to the extent that the allegations of Paragraph 35 of the Complaint are inconsistent with the website or taken out of context, ARL denies the allegations.
36. ARL states that its marketing materials speak for themselves and, to the extent that the allegations of Paragraph 36 of the Complaint are inconsistent with the marketing materials or taken out of context, ARL denies the allegations.
37. ARL states that its marketing materials speak for themselves and, to the extent that the allegations of Paragraph 37 of the Complaint are inconsistent with the marketing materials or taken out of context, ARL denies the allegations.
38. ARL states that its website speaks for itself and, to the extent that the allegations of Paragraph 38 of the Complaint are inconsistent with the website or taken out of context, ARL denies the allegations.
39. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 39 of the Complaint.
40. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 40 of the Complaint.
41. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 41 of the Complaint.
42. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 42 of the Complaint.

43. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 43 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.
44. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 44 of the Complaint.
45. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 45 of the Complaint.
46. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 46 of the Complaint.
47. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 47 of the Complaint.
48. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 48 of the Complaint.
49. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 49 of the Complaint.
50. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 50 of the Complaint.
51. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 51 of the Complaint.
52. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 52 of the Complaint.

53. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 53 of the Complaint.

54. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 54 of the Complaint.

55. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 55 of the Complaint.

56. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 56 of the Complaint.

57. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 57 of the Complaint.

58. ARL denies the allegations set forth in Paragraph 58 of the Complaint.

59. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 59 of the Complaint.

60. ARL denies the allegations set forth in Paragraph 60 of the Complaint.

61. ARL denies the allegations set forth in Paragraph 61 of the Complaint.

62. ARL states that USP 71 speaks for itself. ARL is without knowledge of the size of the subject batch and, therefore, to the extent that the allegation in Paragraph 62 suggests that ARL was acting in a manner inconsistent with USP 71, the allegation is denied.

63. ARL denies the allegations set forth in Paragraph 63 of the Complaint.

64. ARL denies the allegations set forth in Paragraph 64 of the Complaint.

65. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 65 of the Complaint as they relate to the other



defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL. ARL further states that its microbiology reports and marketing materials speak for themselves and, to the extent that the allegations of Paragraph 65 of the Complaint are inconsistent with the microbiology reports and marketing materials or are taken out of context, ARL denies the allegations.

66. ARL denies the allegations set forth in Paragraph 66 of the Complaint.

67. ARL denies the allegations set forth in Paragraph 67 of the Complaint.

68. ARL denies the allegations set forth in Paragraph 68 of the Complaint because the allegations in this paragraph do not accurately reflect the substance and context of Dr. Kupiec's article.

69. ARL denies the allegations set forth in Paragraph 69 of the Complaint because the allegations in this paragraph do not accurately reflect the substance and context of Dr. Kupiec's article.

70. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 70 of the Complaint.

71. ARL denies the allegations set forth in Paragraph 71 of the Complaint.

72. ARL denies the allegations set forth in Paragraph 72 of the Complaint.

73. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 73 of the Complaint.

74. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 74 of the Complaint.

**B. GENERAL ALLEGATIONS DEFENDANTS KNOWINGLY OPERATED BEYOND THE SCOPE OF THEIR LICENSES.**

75. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 75 of the Complaint.

76. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 76 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

**C. DEFENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN DEPORABLE NON-COMPLIANT FACILITY.**

77. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 77 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

78. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 78 of the Complaint.

79. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 79 of the Complaint.

80. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 80 of the Complaint.

81. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 81 of the Complaint.

82. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 82 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

83. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 83 of the Complaint.

84. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 84 of the Complaint.

85. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 85 of the Complaint.

86. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 86 of the Complaint.

87. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 87 of the Complaint.

88. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 88 of the Complaint.

89. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 89 of the Complaint.

90. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 90 of the Complaint.

91. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 91 of the Complaint.

92. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 92 of the Complaint.

**D. DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS.**

93. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 93 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

94. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 94 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

95. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 95 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

96. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 96 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

**E. DEFENDANTS WANTONLLY EXPOSED PLAINTIFFS TO THIS TOXIN.**

97. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 97 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

98. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 98 of the Complaint.

99. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 99 of the Complaint.

100. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 100 of the Complaint.

101. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 101 of the Complaint.

102. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 102 of the Complaint.

103. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 103 of the Complaint.

104. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 104 of the Complaint.

105. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 105 of the Complaint.

106. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 106 of the Complaint as they relate to the other

defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

107. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 107 of the Complaint.

108. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 108 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

109. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 109 of the Complaint.

110. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 110 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

111. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 111 of the Complaint as they relate to the other defendants or the Plaintiff's in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

112. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 112 of the Complaint.

**COUNT I**  
**NEGLIGENCE**

113. ARL repeats and reasserts its responses to paragraphs 1 through 112 above and incorporates those responses as if specifically set forth herein.

114. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 114 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

115. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 115 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

116. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 116 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

117. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 117 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

118. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 118 of the Complaint as they relate to the other

defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

119. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 119 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

120. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 120 of the Complaint.

121. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 121 of the Complaint as they relate to the other defendants or the Plaintiffs in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

WHEREFORE, because the Plaintiffs have failed to state a viable cause of action for Negligence against ARL, Count I against ARL should be dismissed.

## **COUNT II**

### **NEGLIGENCE PER SE**

122. ARL repeats and reasserts its responses to paragraphs 1 through 121 above and incorporates those responses as if specifically set forth herein.

123. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 123 of the Complaint.

124. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 124 of the Complaint.



125. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 125 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

126. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 126 of the Complaint as they relate to the other defendants or the Plaintiffs in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

WHEREFORE, because the Plaintiffs have failed to state a viable cause of action for Negligence Per Se against ARL, Count II against ARL should be dismissed.

### **COUNT III**

#### **NEGLIGENT SUPERVISION**

127. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 127 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

128. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 128 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

129. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 129 of the Complaint as they relate to the other

defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

130. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 130 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

131. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 131 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

132. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 132 of the Complaint as they relate to the other defendants or the Plaintiffs in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

WHEREFORE, because the Plaintiffs have failed to state a viable cause of action for Negligent Supervision against ARL, Count III against ARL should be dismissed.

#### **COUNT IV**

#### **NEGLIGENT MISREPRESENTATION**

133. Since Count IV is not directed at ARL, ARL is not required to respond to paragraphs 133 through 140 of the Complaint. To the extent that any response is required to this paragraph, ARL repeats and reasserts its responses to paragraphs

1 through 133 above and incorporates those responses as if specifically set forth herein.

134. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 134 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

135. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 135 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

136. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 136 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

137. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 137 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

138. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 138 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

139. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 139 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

140. Since Count IV is not directed at ARL, ARL is not required to respond to paragraph 140 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

#### **COUNT V**

#### **BREACH OF IMPLIED WARRANTY**

141. ARL repeats and reasserts its responses to paragraphs 1 through 140 above and incorporates those responses as if specifically set forth herein.

142. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 142 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

143. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 143.

144. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 144 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

145. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 145 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

146. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 146 of the Complaint as they relate to the other defendants or the Plaintiff in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

WHEREFORE, because the Plaintiffs have failed to state a viable cause of action for Breach of Implied Warranty against ARL, Count V against ARL should be dismissed.

#### **COUNT VI**

#### **PUBLIC NUISANCE**

147. Since Count VI is not directed at ARL, ARL is not required to respond to paragraphs 147 through 156 of the Complaint. To the extent that any response is required to this paragraph, ARL repeats and reasserts its responses to paragraphs 1 through 146 above and incorporates those responses as if specifically set forth herein.

148. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 148 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

149. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 149 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

150. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 150 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

151. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 151 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

152. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 152 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

153. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 153 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

154. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 154 of the Complaint. To the extent that any response is required, ARL

is without sufficient knowledge or information to admit or deny the allegations set forth therein.

155. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 155 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

156. Since Count VI is not directed at ARL, ARL is not required to respond to paragraph 156 of the Complaint. To the extent that any response is required, ARL is without sufficient knowledge or information to admit or deny the allegations set forth therein.

## **COUNT VII**

### **LOSS OF CONSORTIUM**

157. ARL repeats and reasserts its responses to paragraphs 1 through 156 above and incorporates those responses as if specifically set forth herein.

158. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 158 of the Complaint.

159. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 159 of the Complaint.

160. ARL is without sufficient knowledge or information to admit or deny the allegations set forth in Paragraph 160 of the Complaint as they relate to the other defendants in the Lawsuit. ARL denies all of the allegations in this paragraph to the extent that they are directed at ARL.

WHEREFORE, because the Plaintiffs have failed to state a viable cause of action for Loss of Consortium against ARL, Count VII against ARL should be dismissed.

WHEREFORE, because the Plaintiff has failed to state a viable cause of action against ARL, the Complaint against ARL should be dismissed.

### **AFFIRMATIVE DEFENSES**

#### **FIRST AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief may be granted against ARL.

#### **SECOND AFFIRMATIVE DEFENSE**

If Plaintiffs have sustained damages, those damages were the result of conduct of individuals over whom ARL had no control and thus for whom ARL is not responsible.

#### **THIRD AFFIRMATIVE DEFENSE**

The Complaint is barred because any acts or omissions of ARL were not the legal or proximate cause of any damage to Plaintiffs.

#### **FOURTH AFFIRMATIVE DEFENSE**

The Complaint is barred by failure to join a party necessary for just adjudication of this action.

#### **FIFTH AFFIRMATIVE DEFENSE**

ARL has performed and fulfilled any and all promises or obligations under any and all applicable contracts, agreements, rules, laws, regulations, and/or ordinances.



**SIXTH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims against ARL are barred because the alleged losses were caused by the conduct of others.

**SEVENTH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims are barred because the alleged losses were caused by the intervening and/or superseding acts of third persons for whom ARL was not responsible.

**EIGHTH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims against ARL should be dismissed for improper venue.

**NINTH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims against ARL should be dismissed for forum non-conveniens.

**TENTH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims should be dismissed for lack of subject matter jurisdiction.

**ELEVENTH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims against ARL should be dismissed for lack of personal jurisdiction.

**TWELTFH AFFIRMATIVE DEFENSE**

The Plaintiffs' claims against ARL should be dismissed due to lack of privity.

**THIRTEENTH AFFIRMATIVE DEFENSE**

ARL reserves the right to amend this Answer and its affirmative defenses, if appropriate, after full investigation and discovery.

**FOURTEENTH AFFIRMATIVE DEFENSE**

ARL avails itself of and adopts such other defenses raised by any other Defendants as may be applicable.

**FIFTEENTH AFFIRMATIVE DEFENSE**

If ARL is found liable, it is severally liable only.

**SIXTEENTH AFFIRMATIVE DEFENSE**

The laws of other jurisdictions apply to this action.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

The Plaintiff's claims against ARL should be dismissed because ARL did not owe or breach any duty to Plaintiffs.

**WHEREFORE**, ARL respectfully requests that this Honorable Court issue an order dismissing the claims against ARL and awarding ARL the reasonable attorneys' fees and costs it has incurred in the defense of this action.

**JURY DEMAND**

ARL demands a trial by jury on all issues.

Respectfully submitted,

<p>Dated: April 17, 2013</p>	<p><b>ARL BIOPHARMA, INC. d/b/a ANALYTICAL RESEARCH LABORATORIES</b> By its attorneys,</p> <hr/> <p>Kenneth B. Walton, BBO #562174 <a href="mailto:kwalton@donovanhatem.com">kwalton@donovanhatem.com</a> Kristen R. Ragosta, BBO #664362 <a href="mailto:kragosta@donovanhatem.com">kragosta@donovanhatem.com</a> DONOVAN HATEM LLP Two Seaport Lane, 8<sup>th</sup> Floor Boston, MA 02210 Tel: (617) 406-4500 Fax: (617) 406-4501</p>
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**CERTIFICATE OF SERVICE**

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on April 17, 2013 using the ECF system that sent notification of this filing to all ECF— registered counsel of record via e-mail generated by the Court's ECF system.

/s/ Kristen R. Ragosta  
*Attorney for ARL Bio Pharma, Inc. d/b/a*  
*Analytical Research Laboratories*

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